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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,787	04/03/2002	Mohamed El-Sherbeini	20522P	1046
210	7590	12/22/2003	EXAMINER	
MERCK AND CO INC P O BOX 2000 RAHWAY, NJ 070650907			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/089,787	EL-SHERBEINI ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 October 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 10-16 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3,4 and 6-9 is/are rejected.
- 7) Claim(s) 2 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 03 April 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>101003</u> . | 6) <input checked="" type="checkbox"/> Other: <i>See Continuation Sheet</i> . |

**DETAILED ACTION**

**Election**

1) Acknowledgment is made of Applicants' election filed 10/08/03 in response to the lack of unity mailed 09/12/03. Applicants have elected invention I, claims 1-4 and 6-9 without traverse. The elected invention is directed to an isolated polynucleotide encoding a polypeptide having SEQ ID NO: 2, or that is complementary to the polynucleotide or that hybridizes with the polynucleotide, a cDNA, an expression vector and a host cell comprising the same. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

**Status of Claims**

2) Claims 1-16 are pending.

Claims 5 and 10-16 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-4 and 6-9 have been elected and are under examination. A First Action on the Merits on these claims is issued.

**Sequence Listing**

3) Acknowledgment is made of Applicants' submission of raw sequence listing and CRF which have been entered on 11/18/02.

**Information Disclosure Statement**

4) Acknowledgment is made of Applicants' Information Disclosure Statement filed 10/10/03. The information referred to therein has been considered and a signed copy is attached to this Office Action.

**Priority**

5) The instant application is a national stage 371 application of PCT/US00/27056, filed 09/29/2000, and claims priority to the provisional application, 60/157,580 filed 10/04/1999 in the United States.

**Specification**

6) The specification is objected to for the following reasons:

(i) The specification lacks a first paragraph that provides priority information as shown

above under the section 'Priority'.

(ii) The use of the trademarks in the instant specification has been noted in this application. For example, page 8, lines 20 and 21: "Qiagen"; "Novagen"; 'Invitrogen' and 'Pharmacia'; page 10, line 28: 'Qiagen'; page 12, lines 14 and 15: 'Packard TriCarb'; and page 12, line 9: 'Triton X-100'. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

**Rejection(s) under 35 U.S.C. § 101**

7) 35 U.S.C. § 101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

8) Claims 6-9 and those that depend therefrom are rejected under 35 U.S.C. § 101 as being directed to a non-statutory subject matter.

Claim 6 does not sufficiently distinguish the claimed cDNA or polynucleotide over a naturally occurring cDNA or polynucleotide as it exists naturally, because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of --An isolated ..-- if descriptive support exists for such a limitation in the instant application, as originally filed. See MPEP 2105.

**Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

10) Claims 1-4 and 6-9 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant(s) regards as the invention.

(a) Claims 1(c) and 6(c) lack proper antecedent basis in the recitation 'a polynucleotide of (a) or (b)'. For proper antecedence, it is suggested that Applicants replace the recitation with --the polynucleotide of (a) or (b)'.

(b) Claim 1(b) and claim 6(b) are vague and indefinite in the recitation: 'complementary to the polynucleotide (a)', because it is unclear whether the complementary polynucleotide is partially complementary or fully complementary to the polynucleotide of (a).

(c) Claims 1(c) and 6(c) are vague and indefinite in the recitation "under stringent conditions". What conditions qualify as 'stringent conditions' is not clear. Does this limitation encompass low, medium or high stringency conditions?

(d) Claim 3 lacks proper antecedent basis in the recitation: 'a polynucleotide of claim 1'. For proper antecedence, it is suggested that Applicants replace the recitation with --the polynucleotide of claim 1'.

(e) Claim 7 lacks antecedence for the recitation 'cDNA in accordance with claim 6'. For proper antecedence, it is suggested that Applicants replace the recitation with --The cDNA in accordance with claim 6--.

(f) Claims 2-14 and 7-10, which depend directly or indirectly from claim 1 or claim 6, are also rejected as being indefinite, because of the vagueness or indefiniteness identified above in the base claim.

#### **Rejection(s) under 35 U.S.A. § 102**

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

12) Claims 1, 3, 4 and 6-9 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Rubenfield *et al.* (US 6,551,795 B1 - Applicants' IDS).

Rubenfield *et al.* disclosed an isolated cDNA or polynucleotide encoding a polypeptide having 98.7% structural identity with the instantly claimed polynucleotide of SEQ ID NO: 1, an

expression vector and a host cell comprising the same. See the attached sequence search report; 'Summary of the Invention'; columns 10-12; Exemplification; and claims. That the prior art polynucleotide with a sequence identity as high as 98.7% is complementary to the instantly claimed polynucleotide of SEQ ID NO: 1 and is expected to hybridize with the instantly claimed polynucleotide of SEQ ID NO: 1 under stringent conditions is inherent from the teachings of the prior art.

Claims 1, 3, 4 and 6-9 are anticipated by Rubenfield *et al.*

### **Objection**

- 13)** Claim 2 is objected to for being dependent from the rejected claim 1.

### **Remarks**

- 14)** Claims 1, 3, 4 and 6-9 stand rejected.

- 15)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center receives transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

- 16)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December, 2003

  
**S. DEVI, PH.D.**  
**PRIMARY EXAMINER**

Continuation of Attachment(s) 6). Other: Sequence search report (3 pages).

Sec 1D NO. 1.

RESULT 1  
US-09-252-991A-7929/c  
Sequence 7929, Application US/09252991A  
Patent No. 6551195  
GENERAL INFORMATION:  
APPLICANT: Marc J. Rubenfield et al.  
TITLE OF INVENTION: NUCLEAR ACID AND POLYNUCLEAR ACID FOR DIFFERENTIATING AERUGINOSA FROM DIF  
FILE REFERENCE: 107196\_1336  
CURRENT APPLICATION NUMBER: US/09/2525.5  
FIRST FILING DATE: 1999-02-18  
PRIOR APPLICATION NUMBER: US 60/074,798  
PRIOR FILING DATE: 1998-02-18  
PRIOR APPLICATION NUMBER: US 60/094,198  
PRIOR FILING DATE: 1998-07-27  
NUMBER OF SEQ ID NOS: 33142  
SEQ ID NO: 7929  
LENGTH: 1170  
TYPE: DNA  
ORGANISM: Pseudomonas aeruginosa  
US-09-252-991A-7929

Query Match	Best Local Similarity	Score	DB 4;	Length	1170;
	Matches 1074;	Pred. No.	1..4e-229;		
	Conservative	0;	Mismatches	9;	Indels
Qy					
1	ATGCTCTTGTCTGGCGGAATACCTGCAACAGTTCTAACAGGCTTCGGCGCTCTCCAG	60			
Db	AATGCTCTGCTCTGGCGAAATACCTGCAACAGTTCTAACAGGCTTCGGCGCTCTCCAG	1167			
Qy	TACCTGACCTCTGCGGCCATTCTCAGGGTGTCAACCGGCTGTCGCTGCTGCTGCTGCTG	61			
Db	TACCTGACCTCTGCGGCCATTCTCAGGGTGTCAACCGGCTGTCGCTGCTGCTGCTGCTG	1107			
Qy	GGGCCCCGGATCTGGTACCTTGCGATCTCCCGATCCCCGATGGGCAAGGGCTGTGCCAACGAC	121			
Db	GGGCCCCGGATCTGGTACCTTGCGATCTCCCGATCCCCGATGGGCAAGGGCTGTGCCAACGAC	1047			
Qy	GTTCCCGAGTGGCACCTGTGCAAGAAGGACCCCCAACATGGCCGCCCTGATCCCT	181			
Db	GTTCCCGAGTGGCACCTGTGCAAGAAGGACCCCCAACATGGCCGCCCTGATCCCT	987			
Qy	ACGGCATAGGCCATGCCGACCTGCACTGGTCTGCTGCTGCTGCTGCTGCTGCTGCTGCTG	241			
Db	ACGGCATAGGCCATGCCGACCTGCACTGGTCTGCTGCTGCTGCTGCTGCTGCTGCTGCTG	927			
Qy	GTGCGGTGCTGGTACCTGCGTCTGGTCTGGTCTGGTCTGGTCTGGTCTGGTCTGGTCTGGT	301			
Db	GTGCGGTGCTGGTCTGGTCTGGTCTGGTCTGGTCTGGTCTGGTCTGGTCTGGTCTGGTCTGGT	867			

361	ATCGAGAAACTCCGCGTTCCTCATGAGTCTTGAGACTTCTTGAGCTGGACCACTCTG	420
807	ATCGAGAAGAACCTCCGCGTTCCTCATGAGTCTTGAGACTTCTTGAGCTGGACCACTCTG	748
421	GCGATGGGCCCGTTCCTCATGAGTCTTGAGACTTCTTGAGCTGGACCACTCTG	480
	747 GCGATGGGCCCGTTCCTCATGAGTCTTGAGACTTCTTGAGCTGGACCACTCTG	688
481	ATCTGCGSATGCTGAAGAGCTGATCCAGTGGSCATCTTCTCTGTGTCCTCTGACCC	540
687	ATCTGCGSATGCTGAAGAGCTGAGATCCAGTGGSCATCTTCTCTGTGTCCTCTGACCC	628
541	TACTCTGCTATCGTGGCTGACAACTCACCAGCTGACCTCTGCTTAACACCTATCTGACCC	600
627	TACTCTGCTATCGTGGCTGACAACTCACCAGCTGACCTCTGCTTAACACCTATCTGACCC	568
601	GCGATCATGCTCCGAGGGTAATGGTTGCCGGCCCTGGCATCTCTCTGCTTAACCTGACCC	660
567	GGGATCAAGCCGAGGGTAATGGTTGCCGGCCCTGGCATCTCTCTGCTTAACCTGACCC	508
661	AACCTGAACTTCGCGSATCCTCTGATTCTCAACCTACCGGGCGGGGGAGCTGATCTG	720
507	AACCTGAACTTCGCGSATCCTCTGATTCTCAACCTACCGGGCGGGGGAGCTGATCTG	448
Qy	721 GTGTCTGCCCCCTGCTGCTGGGACCCCTGGCTCTCTGCTTAACACCTATCTGACCC	780
Db	447 GTGTCTGCCCCCTGCTGCTGGGACCCCTGGCTCTCTGCTTAACACCTATCTGACCC	388
Qy	781 CGCGAAGCTTCTCATGGCACCTGGCTGGCTGGCTGGCTGGCTGGCACCTGATCTG	840
Db	387 GCGAGGCTCTCATGGCACCTGGCTGGCTGGCTGGCTGGCACCTGATCTGATCTG	328
Qy	841 GCGGTGATCTGCTGCGCAGGAGATGCTGCTGCTGCTGCTGCTGCTGCTGCTGCTG	900
Db	327 GCGGTGATCTGCTGCGCAGGAAATGCTGCTGCTGCTGCTGCTGCTGCTGCTGCTG	268
Qy	901 ACCCTCTCGTGTGATCTCAGGGTGGCTCTTCAAGTGTGCTGCTGCTGCTGCTGCTG	960
Db	267 ACCCTCTCGTGTGATCTCAGGGTGGCTCTTCAAGTGTGCTGCTGCTGCTGCTGCTG	208
Qy	961 ATGGCGCCGATCTCATCCTACCATTCGAAAGGTGGCTGGCTGGCTGGCTGATCTG	1024
Db	207 ATGGCGCCGATCTCATCCTACCATTCGAAAGGTGGCTGGCTGGCTGATCTGATCTG	148
Qy	1021 CGCTCTGGAATCATCACCGTGTATCTGCTGCTGCTGCTGCTGCTGCTGCTGCTG	1084
Db	147 CGCTCTGGAATCATCACCGTGTATCTGCTGCTGCTGCTGCTGCTGCTGCTGCTG	88
Qy	1081 TGA 1083	
Db	87 TGA 85	

RESULT 2  
US-09-252-991A-7623  
Sequence 7623 Application

US-09-252-991A-7623	Query Match	Best Local Similarity	Matches 1074; Cor
	Qy 1 ATGCTCTT		
	Db 322 ATGCTCTT		
	Qy 61 TACCTCTT		
	Db 382 TACCTCTT		
	Qy 121 GGGCCCCC		
	Db 442 GGGCCCCC		
	Qy 181 GGTCCTCC		
	Db 502 GGTCCTCC		
	Qy 241 ACCGCCCT		
	Db 562 ACCGCCCT		
	Qy 301 GTGCTCTT		
	Db 622 GTGCTCTT		
	Qy 361 ATCGAGAT		
	Db 682 ATCGAGAT		
	Qy 421 GGCATTTT		
	Db 742 GGCATTTT		
	Qy 481 ATCGTGTG		
	Db 802 ATCGTGTG		
	Qy 541 TACTTCTT		
	Db 862 TACTTCTT		
	Qy 601 GCGATTTT		
	Db 922 GCGATTTT		
	Qy 661 AACGTTTG		
	Db 982 AACGTTTG		
	Qy 721 GTGTTCTT		
	Db 1042 GTGTTCTT		
	Qy 781 GCGCACTT		
	Db 1102 GCGCACTT		
	Qy 841 GCGGTTCT		
	Db 1162 GCGGTTCT		
	Qy 901 ACCCTCTT		
	Db 1222 ACCCTCTT		
	Qy 961 ATGGCCAA		
	Db 1282 ATGGCCAA		

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Qy 1021 CGCTTCTGGATCATACCGTGTATCCGGTCTGATTCGGCCTGCCACCTTGAGCTGGT 1080  
Db 1342 CGCTTCTGGATCATACCGTGTATCCGGTCTGATTCGGCCTGCCACCTTGAGCTGGT 1401

Qy 1081 TGA 1083  
Db 1402 TGA 1404